Disulfoton Technical Briefing

February 3, 2000

Introduction and Background Information

Overview

Lois Rossi
Director
Special Review and Reregistration Division

Overview of Day's Activities

- Legal framework and regulatory history
- Provide usage profiles
- Present risk assessments
- Questions and comments

Goals of Meeting

- Provide an understanding of EPA's risk assessments
- Answer your questions
- Identify risks of concern
- Begin risk mitigation dialog

Legal Context

FQPA Amendments to FIFRA Required:

- Reassessment of all existing tolerances
- Aggregate assessments
- Safety factor for children
- Cumulative assessments

EPA Implementation of FQPA

- Formation of Tolerance Reassessment Advisory Committee (TRAC)
- Development of science policies
- Development of pilot process for public participation
- Focus on OP's

TRAC Pilot OP Review Process

- Phase 1 (30 days)
  - Registrant "Error Only" Review
- Phase 2 (up to 30 days)
  - EPA considers registrants' comments
- Phase 3 (60 days)
  - Public comment on preliminary risk assessment

TRAC Pilot OP Review Process

- Phase 4 (90 days)
  - EPA revises risk assessments, holds public meetings/technical briefings
- Phase 5 (60 days)
  - EPA solicits risk management ideas
- Phase 6 (up to 60 days)
  - EPA develops risk management strategies

Introduction

Christina Scheltema
Chemical Review Manager
Special Review and Reregistration Division

Purpose of Briefing

- Present overview of disulfoton revised risk assessment
- Identify areas where mitigation is needed
- Begin next phase of public participation process

Disulfoton Revised Risk Assessments Consider

- Dietary Risk
  - Food
  - Drinking water
- Occupational Risk
  - Handlers
  - Postapplication workers
- Nonoccupational Risk
  - Ornamental and garden use
  - Homeowner handlers
  - Postapplication exposure

Disulfoton Revised Risk Assessments Consider

- Aggregate Risk
  - Dietary
  - Drinking water
  - Residential
- For disulfoton, aggregate risk from food and water alone may be of concern

Disulfoton Revised Risk Assessments Consider

- Ecological Risk
  - Birds
  - Mammals
  - Aquatic Species
- Water Resources
  - Surface water
  - Groundwater

Introduction

TRAC Public Participation Process for Disulfoton

Phase	Initiated	Completed
① Registrant "Error Only" Review	11/98	12/98
② EPA Considers Registrant's Comments	12/98	1/99
③ Public Comment Period	1/99	3/99
④ EPA Revises Risk Assessment	3/99	2/00
⑤ Solicit Risk Management Ideas	2/00	
⑥ Develop Risk Management Strategy		

Public Participation Process for Disulfoton

- ❖Phase 1: Registrant "Error Only" Review
- ❖Phase 2: EPA Considers Registrant's Comments
- ❖Phase 3: Public Comment on Preliminary Risk Assessment

Phase 3: *Public Comment on Preliminary Risk Assessment*

- Comments from registrant, grower groups, other stakeholders
- Comments focused on importance and benefits to agriculture
- Comments on agency policies, assumptions, and methodologies
- Submission of additional data

Phase 4: *EPA Revises Risk Assessment*

- Dietary
  - Acute: Highly refined, probabilistic (Monte Carlo)
  - Chronic: Refined to include % crop treated, field trial or monitoring data

Phase 4: *EPA Revises Risk Assessment*

- Residential
  - Changes to assessment
  - Considered proposed deletion of home garden use
- Aggregate
  - Refinements in food residues allowed water to be included

Phase 4: *EPA Revises Risk Assessment*

- Occupational
  - Considers mitigation proposal from registrant

Phase 4: *EPA Revises Risk Assessment*

- Environmental Fate and Water Resources
  - Includes monitoring and modeling data and proposed mitigation
  - Consider mitigation proposal from registrant
- Ecological
  - Incidence data
  - Proposed mitigation

Revised Risk Assessment Sent to USDA

- USDA Conference Call with Stakeholders:
  - Growers
  - Cooperative Extension Agents
  - Land Grant Universities
  - Registrant
  - USDA Regional Offices
  - EPA

Revised Risk Assessment Sent to USDA

- USDA Conference Call on Disulfoton
  - December 17, 1999
- Comments and Discussion Included:
  - Use and usage
  - Underlying assumptions
  - Areas where new or better information can be provided

Phase 5: *Solicit Risk Management Ideas*

- Technical briefing (February 2000)
- Revised risk assessment will be available in the public docket and on the internet
- Begin 60-day public participation period
- Public submits risk management ideas
- Opportunities for stakeholders to meet with EPA

Registrant's Proposed Label Changes (1999)

- Reduce number of applications
- Reduce application rates
- Limit total amount allowed per season on tobacco
- Eliminate foliar application on cotton
- Cancel uses on:
  - home vegetable gardens
  - tomatoes
  - oats
  - corn
  - pecans

NOTE: See http://www.epa.gov/pesticides/op/disulfoton.htm

Regulatory History for Disulfoton

- Registered as an insecticide in 1961
- Registration Standard published in 1984
- Now registered on over 35 crops
- 50 tolerances to be reassessed in the RED

Use-Related Information

Don Atwood, Ph.D.
Entomologist
Biological and Economic Analysis Division

Use Profile

- Class:
  - Organophosphate Insecticide/Acaricide
- Mode of Action:
  - Acetylcholinesterase inhibition

Use Profile: *End-Use Products*

- Emulsifiable concentrate (23-65% ai)
- Ready-to-use liquid (95% ai)
- Granular (0.37-15% ai)
- Pellet/Tablet (1-2% ai)
- Impregnated material (1% ai)

Use Profile: *Uses*

- Food and Feed Crops
  - alfalfa (feed), asparagus, broccoli, Brussels sprouts, cabbage, Chinese cabbage, cauliflower, coffee, clover (feed), lettuce, pecan, pepper, barley, dried beans, succulent beans (lima and snap), corn (field, pop, and sweet), cotton, lentils, oats, peanuts, peas, potato, sorghum, soybeans, triticale, wheat, tomatoes

Use Profile: *Uses* (con't)

- Non-food Crops
  - non-bearing fruit trees (apple, crabapple, pear, apricot, cherry, peach, plum and prune), Christmas trees, ornamentals (flowers, plants, shrubs, and trees), strawberry (propagating plants only), and raspberry (nursery stock only)

Use Profile: *Application Equipment*

- Aircraft
- Ground sprayer (high and low volume)
- Drip and sprinkler irrigation
- Soil injector
- Hand (shaker can and measuring container)

Use Profile: *Application Methods*

- Broadcast
- Chemigation
- Spray (high and low volume)
- Soil band
- Soil in-furrow (drill, injection, and hill drop)
- Soil incorporation by irrigation
- Side and top dressing

Use Profile: *Use Rates*

Use	Rate (lb ai/A)
Most food and feed use	1-2.5
Potato	4
Flower garden	28.6
Pecans	4.5
Non-bearing fruit trees	102

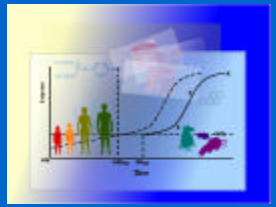
Use Profile: *Typical Usage*

- 1.2 million lbs ai applied annually
- Major Uses On:
  - Cotton (420,000 lbs ai),
  - Wheat (220,000 lbs ai),
  - Potatoes (180,000 lbs ai), and
  - Tobacco (60,000 lbs ai)
- Highest Percent Acres Treated Include:
  - Asparagus (40%) and
  - Christmas trees (NC) (65%)

Use Profile: *Sources of Data*

- USDA/NASS
- California Department of Pesticide Regulation
- National Center for Food and Agricultural Policy
- Bayer Corporation
- US EPA Proprietary databases

Human Health Risk Assessment



Christina Jarvis, EPS
Jonathan Becker, Ph.D
William O. Smith, Ph.D

NOTE: The Human Health Risk Assessment document is at:
http://www.epa.gov/pesticides/op/disulfoton.htm

Dietary Exposure and Risk *(including drinking water)*

Christina Jarvis
William O. Smith, Ph.D
Health Effects Division

Risk Assessment Components

- Dietary
  - Food
  - Drinking water
- Occupational
  - Handlers (crops and non-food plants)
  - Postapplication workers
- Non-Occupational
  - Residential (gardens, shrubs and small trees)
- Aggregate (food, drinking water, residential)

Basic Dietary Risk Equation

Risk = Hazard x Exposure, where

Exposure = Consumption x Residue

Effect Levels

- Lowest Observed Adverse Effect Level = LOAEL
  - *Is the lowest dose at which an adverse health effect is seen. Has units of mg per kg body weight per day (mg/kg/day)*
- No Observed Adverse Effect Level = NOAEL
  - *Is the highest dose at which no adverse health effect is seen. This dose is less than the LOAEL. Has units of mg per kg body weight per day (mg/kg/day)*

Acute Hazard (toxicity)

Study:	Acute neurotoxicity in rats
Endpoint:	muscle fasciculation, plasma and red blood cell cholinesterase inhibition within 24 hours of a single dose
LOAEL:	0.75 mg/kg/day
NOAEL:	0.25 mg/kg/day

NOTE: *Endpoint from this study most accurately reflects toxicity which could result from one-day dietary exposure to disulfoton*

Chronic Hazard (toxicity)

Study:	One-year toxicity study in dogs
Endpoint:	Plasma Cholinesterase Inhibition
LOAEL:	0.094 mg/kg/day
NOAEL:	0.013 mg/kg/day

NOTE: *Endpoint from ths study most accurately reflects toxicity that could result from long-term dietary exposure to disulfoton.*

Analysis of Special Susceptibility of Infants and Children

- No developmental effects in fetuses only at maternally-toxic dose levels
- No malformations of the fetal nervous system
- No increased susceptibility in pups relative to adults
- No neuropathy seen in neurotoxicity studies or other studies where it was assessed
- Complete toxicity database

Uncertainty and Safety Factors

- 10X Interspecies Variability
- 10X Intraspecies Sensitivity
- 1X FQPA Safety Factor

- 100X Total Uncertainty and Safety Factors for all Dietary Risk Assessments

Reference and Population Adjusted Doses

$$RfD = \frac{NOAEL}{UF}$$

$$PAD = \frac{RfD}{FQPA\ Safety\ Factor}$$

$$\%PAD = \frac{Exposure}{PAD} \times 100$$

Acute and Chronic Population Adjusted Doses (aPAD and cPAD)

- aPAD = 0.0025 mg/kg/day, based on:
  - NOAEL of 0.25 mg/kg/day
  - 100X Uncertainty Factor
- cPAD = 0.00013 mg/kg/day, based on:
  - NOAEL of 0.013 mg/kg/day
  - 100X Uncertainty Factor

Dietary (Food) Risk Assessment: *Summary*

- Acute
  - Highly refined probabilistic assessment
  - Risk estimates are below the level of concern
- Chronic
  - Highly refined
  - Risk estimates are below the level of concern

Source of Data

- Consumption Data
  - USDA's Continuing Survey of Food Intake by Individuals (CSFII) 1989-91 Data

Source of Data

- Residue Data
  - Residue monitoring data (FDA, PDP)
  - Field trial data, livestock feeding studies
  - Food processing and preparation data
  - Pesticide usage data (percent of crop treated)

Residues of Concern

- Disulfoton
- Disulfoton sulfoxide
- Disulfoton sulfone
- Demeton-S
  (Disulfoton oxygen analog)
- Demeton-S sulfoxide
- Demeton-S sulfone

Residue Data Sources for Refined Risk Assessment

- FDA Surveillance Monitoring Data
- Field Trial Data
- Processing Data
- Livestock Feeding Studies

FDA Monitoring Data Used for Refined Dietary Risk Assessment

- Asparagus
- Beans (dry & succulent[1])
- Broccoli
- Cabbage[2]
- Cauliflower
- Corn (field, pop & sweet)
- Potatoes
- Tomatoes
- Lettuce
- Peas (dry & succulent)
- Sweet peppers

[1]includes lentils
[2]includes Chinese cabbage

Field Trial Data and Tolerances Used for Refined Dietary Risk Assessment

- Field Trial Data
  - Barley
  - Brussels sprouts
  - Coffee[1]
  - Cotton
  - Hops[1]
  - Oats
  - Chili peppers
  - Rice[1]
  - Soybeans
  - Wheat (includes triticale)
  - Peanuts
  - Pecans
- Tolerance Level Residues
  - Sorghum

[1]Import tolerances

Food Processing Data Used for Refined Dietary Risk Assessment

- Generic cooking and canning factors
  - From published studies
- Commodity-specific factors
  - From guideline processing studies on:
    - coffee
    - corn
    - potatoes
    - soybeans
    - tomatoes
    - wheat
- Standard concentration factors

Derivation of Meat and Milk Data Used for Refined Dietary Risk Assessment

- Lactating cows were fed disulfoton for a month
- Feed-to-milk/meat **transfer ratios** were derived
- Transfer ratios were applied to anticipated residues in livestock feed
  - acute ARs for meat & milk based on maximum diet
  - chronic ARs for meat & milk based on average diet

Probabilistic Acute Dietary Analysis Results

Risk Estimates as Percent of the aPAD*

Population	99.9th Percentile
U. S. Population	7.0
Infants	8.7
Children 1-6	9.6
Children 7-12	8.1

*aPAD = 0.0025 mg/kg/day

Chronic Dietary Analysis Results

Risk Estimates as Percent of the cPAD*

Population	%cPAD
U.S Population	2.3
Infants	0.9
Children 1-6	3.5
Children 7-12	2.4

*cPAD = 0.00013 mg/kg/day

Dietary (Food) Risk Assessment: *Summary*

- Acute
  - Highly refined
  - Acute risk estimates are below the level of concern
- Chronic
  - Highly refined
  - Chronic risk estimates are below the level of concern

Drinking Water Risk Assessment

- Conducted because of use pattern and environmental fate profile
  - High application rates
  - Degradates more persistent than parent
- Available drinking water monitoring data limited
- Drinking water assessment is based on simulation modeling (screening model) for surface water (Tier 2 PRZM/EXAMS) and monitoring data for groundwater

Drinking Water Risk Assessment

- Acute (for children 1-6)
  - 10% of the acute PAD used by exposure through food, leaving 90% for drinking water exposure
- Chronic (for children 1-6)
  - 4% of chronic PAD used by exposure through food, leaving 96% for drinking water exposure
- Estimated environmental concentrations of disulfoton in drinking water may exceed the Agency's level of concern for most uses

Occupational and Residential Exposure and Risk Assessment

Jonathan Becker, Ph.D.
Environmental Health Scientist
Health Effects Division

Occupational Risk Assessment

- Handlers
  - *Professional pesticide applicators and farmer/growers who mix, load and apply pesticides*
- Postapplication Workers
  - *Workers who prune, thin, hoe, prop, and harvest crops following pesticide application*

Hazard Identification

- Acutely toxic (Category 1) by all routes
- Endpoints Used for Dermal Risk Assessments:

Short-Term	NOAEL	0.4 mg/kg/day (21-day dermal study in rabbits)
	LOAEL	1.6 mg/kg/day, based on brain, plasma, and red blood cell cholinesterase inhibition
Intermediate-Term	NOAEL	0.03 mg/kg/day (6 month oral study in rats)
	LOAEL	0.06 mg/kg/day based on brain, plasma, and red blood cell cholinesterase inhibition
Dermal Absorption		estimated to be 36% of the oral equivalent

Hazard Identification (con't)

- Inhalation Endpoints (all time periods):

NOAEL	0.00016 mg/L (90 day inhalation study in rats)
LOAEL	0.0014 mg/L based on brain, plasma, and red blood cell cholinesterase inhibition

Uncertainty and Safety Factors

- 10X Interspecies Variability
- 10X Intraspecies Sensitivity
- 1X FQPA Safety Factor

Target MOE's

- 100 for both residential and occupational risk assessments

Occupational Incidents

- California DPR (1982 to 1995)
  - 29 case involving disulfoton
  - Incidents involve mainly handlers
  - Spray drift or reentry cases are uncommon
  - Occupational hazard rates below average
- Poison Control Centers
  - 1985 to 1992 – 29 cases
  - 1993 to 1996 – 17 cases
  - Occupational hazard rates above average

Handler Assessment

- The Handler Risk Assessment Is Based on:
  - Activity (e.g., mixing/loading)
  - Formulation and application equipment
  - Unit exposure (mg ai/lb ai handled)
  - Amount of pesticide handled
  - Level of protection (PPE, engineering controls)
  - Toxicity endpoint

Occupational Handler Assessment

Handler Exposure and Risk Calculations

Dose = (Unit Exposure) x (Amount Handled) x (Absorption)
Body Weight

Unit Exposure. *Derived from PHED unless chemical-specific data are available.*

Amount Handled. *Label information (e.g., application rate and frequency); standard assumptions on number of days worked, etc.*

Absorption. *Assumed to be 100 percent unless dermal absorption study shows lower percent dermal absorption*

Body Weight. *Standard value: 70 kg for males; 60 kg females*

MOE = NOAEL (mg/kg/day)
Dose (mg/kg/day)

Handler Assessment

- Data Sources:
  - Labels
  - Use information
  - Standard values
  - Chemical-specific studies
  - Pesticide Handlers Exposure Database (PHED)

Handler Assessment Scenarios: *Emulsifiable Concentrate (EC) Formulation*

- Mixer/Loader:
  - Aerial
  - Chemigation
  - Groundboom
  - Airblast
- Applicator
  - Aerial
  - Groundboom
  - Airblast
- Flagger
  - Aerial Applications
- Mixer/Loader/ Applicator
  - Ready-to-Use for Seed Soak

Handler Assessment Scenarios: *Granular Formulation*

- Mixer/Loader
  - Aerial
  - Tractor-drawn spreader
- Applicator
  - Aerial
  - Tractor-drawn spreader
  - Hand
- Flagger
  - Aerial applications
- Mixer/Loader/ Applicator
  - Belly grinder
  - Push-type spreader

Occupational Handler Assessments

- Based on Acute Toxicity Categories, the Current Labels Require:
  - Long-sleeved shirt, long pants, coveralls
  - Chemical-resistant gloves, footwear, socks, headgear, and apron
  - Respirator
  - Closed mixing/loading for aerial and chemigation
  - Enclosed cab truck for flaggers

Handler Risks from Granular Formulations

Scenario	Range of MOE's		
	Mixer/Loader	Applicator	Flagger
Aerial	2.1 -- 100+	2.0 -- 8	3.3 -- 55
Tractor-Drawn Spreader	2.3 -- 100+	2.0 -- 100+	
Push Spreader	0.02 -- 19		
Belly Grinder	0.003 -- 0.8		
Hand	0.8 -- 3.8		

Handler Risks from Liquid Formulations

Scenario	Range of MOE's		
	Mixer/Loader	Applicator	Flagger
Aerial	1.0 -- 17	3.3 -- 29	1.6 -- 30
Groundboom	2.1 -- 75	1.6 -- 100+	
Airblast	2.8 -- 25	0.2 -- 1.6	
Chemigation	0.3 -- 2.9		

Handler Risk Assessment Summary

- Seed soak scenario lacks exposure data
- Estimated handler risks exceed EPA's level of concern for most scenarios
- Registrant proposals to reduce application rates will not mitigate the Agency's concern about worker risk

Occupational Postapplication Assessment

- Postapplication Risk Assessment Is Based On:
  - Dislodgeable Foliar Residue (DFR):
    - *Amount of pesticide residue that workers contact.*
  - Transfer Coefficient (TC):
    - *Indicator of amount of foliar contact that a worker has for each crop and activity.*
  - Absorption, hours worked per day, body weight.

Occupational Postapplication Assessment

Exposure and Risk Calculations

$$\text{Dose} = \frac{\text{DFR} \times \text{Transfer Coefficient} \times \text{Hrs Worked} \times \text{Absorption}}{\text{Body Weight (kg)}}$$

DFR. *Measured in a study. This is chemical-specific. There is a Task Force generating data.*

Transfer Coefficient. *Standard values for a number of activities. When actual data are available, this is calculated specifically.*

Hrs Worked. *Standard value.*

Absorption. *Assumed to be 100 percent unless dermal absorption study shows lower percent dermal absorption.*

Body Weight. *Standard value: 70 kg for males; 60 for females*

$$\text{MOE} = \frac{\text{NOAEL (mg/kg/day)}}{\text{Dose (mg/kg/day)}}$$

Occupational Postapplication Assessments

- Sources of Information:
  - Dislodgeable Foliar Residue Data
    - Standard values
    - Chemical-specific studies
  - Transfer Coefficients
    - Standard values
    - Chemical-specific studies
  - Exposure Factors
    - Standard values

Occupational Postapplication Assessment

- Postapplication Exposure Scenarios:
  - Harvesting nut trees
  - Harvesting low-growing field crops
  - Weeding, scouting, or other non-harvesting activities
  - Transplanting, harvesting, and pruning ornamentals

Occupational Postapplication Assessment

- Based on chemical-specific data, postapplication risks are low when disulfoton is soil-incorporated at low application rates
- Insufficient data are available to assess risks at higher application rates
- Estimated Reentry Intervals (REIs) range from 28 to 32 days for non-bearing fruit trees, flowers, ground covers, and raspberry crops with application rates greater than 4 lbs ai/A

Residential Incidents

- Poison Control Centers
  - 1985 to 1992 (1301 exposures):
    - 157 adult cases, 36 children < 6 years old
  - 1993 to 1996 (570 exposures):
    - 86 adult cases; 12 children < 6 years old
- 1989 Analysis of 220 Consumer Pesticide Products
  - 2% Disulfoton was 3rd most toxic of all products
  - 1% Disulfoton was 7th most toxic of all products
  - Of all Ready-To-Use (RTU) products, these products rank as the most toxic

Residential Assessments

- Handlers
  - *Individuals involved with non-occupational pesticide applications in and around their residences*
- Postapplication
  - *Adults and children that could be exposed because of activities in and around their residences*

Residential Handler Assessment

- Exposure Scenarios:
  - Belly grinder
  - Push-type granular spreader
  - Spoon, cup, hand
  - Insecticidal spikes

Residential Handler Risks

Scenario	MOE's
Belly Grinder	0.1 – 0.3
Push Spreader	0.3 – 100+
Spoon/Hand	0.002 - 13

Residential Handler Assessment

- No exposure data available to evaluate use of insecticidal spikes
- Risks to residential handlers exceed the EPA's level of concern for all scenarios except for loading/applying granular formulations to ornamentals with a push-type spreader at the lowest application rates

Residential Postapplication Assessment

- Exposure Scenarios:
  - Transplanting, hoeing, weeding treated ornamental trees and shrubs
  - Weeding, hoeing home-grown vegetable crops
  - Incidental soil ingestion

Residential Postapplication Assessment

- EPA has no exposure data to assess postapplication contact with treated soil but believes potential exposure to adults to be low
- Estimated risks from soil ingestion by toddlers do not exceed EPA's level of concern

Aggregate Risk

Christina Jarvis
Environmental Protection Specialist
Health Effects Division

Aggregate Risk Assessment

- Aggregate risk assessment of disulfoton currently includes food and drinking water only
- Both children and adults considered

Aggregate Risk Assessment: *Results*

- Acute & Chronic Aggregate
  - Food and water only
  - Food exposure not of concern
  - Drinking water exposure based on modeling and limited monitoring data may be of concern

Aggregate Risk Assessment: *Results*

- Short-term (food, water & residential)
  - Not combined because residential uses alone exceed the level of concern

Ecological Assessment

James Wolf, Ph.D
Henry Craven

Environmental Assessment Overview
Environmental Fate

James Wolf, Ph.D.
Environmental Scientist
Ecological Fate and Effects Division

Environmental Risk Assessment

- Environmental Fate Assessment
  - Lab and field studies to characterize persistence and mobility
- Water Resources Assessment
  - Use monitoring and modeling to estimate potential exposure

Environmental Risk Assessment

- Ecological Toxicity
  - Lab (acute and chronic) studies to determine toxicity to terrestrial and aquatic organisms
- Ecological Risk Assessment
  - Compare exposure estimates to ecological toxicity to determine potential effects
- Ecological Risk Characterization
  - Refine risk assessment using field studies and incident reports and usage information

Disulfoton Environmental Fate

- Parent not Persistent
  - Stable to hydrolysis
  - Breaks down in light: *half-life 4 days*
  - Metabolized by soil microbes: *half-life ~5 days*
  - Verified with field dissipation study: *half-life 2-4 days*
- Parent not Mobile
  - Low mobility, but detected in groundwater (highly vulnerable areas)
- Lack data on anaerobic and aerobic aquatic metabolism/degradation

Disulfoton Environmental Fate (con't)

- Degradates:

  disulfoton → *sulfoxide* → *sulfone*

- More persistent and mobile than parent
  - **Sulfoxide**: 1% of applied left after 367 days
  - **Sulfone**: 35 % of applied left after 367 days
  - **Both** found at 18" in field dissipation study
  - High potential to reach ground and surface water
- Lack adsorption/desorption data to confirm degradate mobility

Drinking Water Assessment

Modeling Surface Water

PRZM and EXAMS Parent Disulfoton & Total Disulfoton (including sulfoxide and sulfone)

	EEC's	
	Peak (µg/L)	**Annual Mean (µg/L)**
Disulfoton	26.75	1.14
Total Residues	58.47	9.32

Drinking Water Assessment

Modeling Ground Water

- SCI-GROW model used for parent & total disulfoton (including sulfoxide and sulfone)
  - Parent disulfoton: 0.05 µg/L
  - Of total disulfoton: 3.19 µg/L

Drinking Water Assessment

Monitoring Surface Water

- Few detections of parent disulfoton in surface water
  - NAQWA 0.01 to 0.060 µg/L
    - 5,196 samples; 29 > 0.017 µg/L
  - Detections in a Virginia study:
    - 0.37 to 6.22 µg/L at 2 of 8 sites
    - Did not analyze for the disulfoton degradates sulfoxide and sulfone

Drinking Water Assessment

Monitoring Ground Water

- Monitoring Data Show Limited Detections of Parent Disulfoton
  - Virginia:
    - 0.04 to 2.87 µg/L at 5 of 8 sites
  - Wisconsin: 4.00 to 100.00 µg/L
    - 25 wells; 14 of 29 samples with detects
    - Higher than SCI-GROW EEC
    - Highly vulnerable area
    - QA/QC uncertainty

Drinking Water Assessment

- Drinking Water EECs (based on modeling and monitoring):

	Surface Water (µg/L)		Ground Water (µg/L)
	Acute	Chronic	
Disulfoton	26.75	1.14	2.87[1]
Total Residues	58.47	9.32	3.19

[1]based on monitoring

Drinking Water Assessment

- Monitoring Uncertainties:
  - Different limits of detection among studies
  - Frequently high limits of detection
  - Lacking information concerning disulfoton use around sampling sites
  - Lacking information to characterize the hydrogeology of the study sites
  - Degradates (sulfoxide and sulfone) are rarely analyzed for

Drinking Water Assessment

- Screening Modeling Uncertainties:
  - The EEC's are accurate only to the extent that the sites represent the hypothetical high-exposure sites
  - The scenarios selected as likely sites to produce high concentrations in aquatic environments
  - The water body simulated may not adequately represent a real water body
  - The quality of the input data and the ability of the model to represent the real world
  - Number of years that were simulated may limit the accuracy and precision of the estimates

Drinking Water Assessment

- Screening Modeling Uncertainties: (con't)
  - The aquatic degradation rate(s) had to be estimated
  - Total disulfoton residue decline rate was estimated from data
  - Mobility ($K_{oc}S$) and hydrolysis rates for sulfoxide and sulfone degradates are not known (assumed to be equal to those of parent)
  - The models were not developed to estimate environmental concentrations in drinking water

Ecological Effects

Henry Craven
Biologist
Ecological Fate and Effects Division

Ecological Effects Overview

- Toxicity Database Is Robust
  - Disulfoton, disulfoton sulfoxide, and disulfoton sulfone
  - Laboratory and field data
- Risk, in Decreasing Order:

  mammals > birds > aquatic invertebrates > fish

Disulfoton Avian and Mammalian Toxicity

- Disulfoton
  - Acute toxicity: moderate to very highly toxic for birds and very highly toxic for mammals

	Birds	Mammals
LC_{50}	333 ppm	No data
LD_{50}	3.2 mg/kg	1.9 mg/kg

Disulfoton Avian and Mammalian Toxicity

- Disulfoton
  - Chronic toxicity: at low exposure levels

	Birds	Mammals
NOAEC	37 ppm	0.8 ppm
LOAEC	74 ppm	2.4 ppm
Effect	Hatchling body weight reduced	Decreases in litter size, pup weight & pup survival

Disulfoton Avian and Mammalian Toxicity (con't)

- Degradates (sulfoxide degradate and sulfone degradate)
  - Slightly less toxic than parent
  - No chronic toxicity data with degradates

	Birds	Mammals
Sulfoxide		
LC_{50}	456 ppm	no data
LD_{50}	9.2 mg/kg	no data
Sulfone		
LC_{50}	558 ppm	no data
LD_{50}	18 mg/kg	11.2 mg/kg

Disulfoton Risk to Birds and Mammals

- Risk conclusions based on estimated exposure concentrations
- Sprays (foliar and soil)
  - High acute and chronic risk to birds at >1 lb ai/acre
  - High acute and chronic risk to mammals at all application rates
- Granular formulations
  - High acute risk to birds and mammals at all rates
  - Chronic risk possible, not assessed quantitatively

Disulfoton Bird and Mammal Ecological Risk Characterization

- Additional Factors Considered in Terrestrial Risk:
  - Incidents
  - Field studies
  - Method of application
  - Metabolism information
  - Degradate toxicity

Disulfoton Bird and Mammal Ecological Risk Characterization

- Incident:
  - Swainson Hawks died from ingesting grasshoppers following germination of treated cotton seeds
    - residues in digestive tract approximately 7 ppm
  - Indicates potential risk to sensitive species at relatively low exposure levels

Note: Slide has been changed to correct an error regarding seed treatment use.

Disulfoton Bird and Mammal Ecological Risk Characterization

Field Studies Suggest:

- Spray formulations:
  - At rates >2 lb ai/acre, high risk to birds and mammals
  - At rates <1 lb ai/acre, risk is much lower
- Granular formulations:
  - In field, sparrows averaged 11 granules
    - In lab tests 6 -10 15G granules killed sparrows
  - Avian and mammal mortality at 3 lb ai/acre
  - Risk at lower rates not tested in field

Disulfoton Bird and Mammal Ecological Risk Characterization

- Method of Application
  - Soil application and soil incorporation reduces potential exposure and thus reduces risk
- Risk to liquid formulation based on LD_{50} uncertain: Disulfoton rapidly metabolized
  - Agency requests small mammal dietary LC_{50} test
- Degradates of Disulfoton are nearly as toxic as parent
  - Degradation may not mitigate risk

Disulfoton Beneficial Insect Toxicity

- Honey Bee – Acute Contact

Compound	Toxicity	
	Category	LD_{50} µg/bee
Disulfoton	moderately	4.1
Sulfoxide	moderately	1.1
Sulfone	highly	0.9

- Honey Bee – Foliar Residue
  - Di-Syston 8 EC:
    - No toxic effects to bees at 1.0 lb ai/A

Disulfoton Fish Toxicity

- Acute

Compound	Freshwater		Estuarine	
	Toxicity Category	LC_{50}	Toxicity Category	LC_{50}
Parent	very highly	39 ppb	highly	520 ppb
	moderately	7,200 ppb		
Degradates	Similar to parent		Less toxic than to freshwater species	

Disulfoton Fish Toxicity

- Chronic

	Freshwater	Estuarine
NOAEC	220 ppb	16 ppb
LOAEC	420 ppb	32 ppb
Effect	Reduced growth of larvae	Reduced growth and survival of larvae

Disulfoton Freshwater and Estuarine Invertebrate Toxicity

- Acute

Compound	Freshwater		Estuarine	
	Toxicity Category	EC_{50}	Toxicity Category	EC_{50}
Parent	Very highly Very highly	3.9 ppb 52 ppb	Highly very highly	900 ppb 15 ppb
Degradates	Slightly less than parent			

Disulfoton Freshwater and Estuarine Invertebrate Toxicity

- Chronic

	Freshwater	Estuarine
LOAEC	0.07 ppb	8.26 ppb
Effect	➢ Affects growth and reproduction at low ppb's ➢ Freshwater invertebrates more sensitive than estuarine species ➢ Decreasing Sensitivity for Freshwater: Parent > sulfone > sufoxide	

Disulfoton Aquatic Risk

- Acute risk based on peak concentrations
- Chronic risk based on long-term average concentrations
- Summary and Conclusion:
  - Freshwater invertebrates at much higher chronic risk than fish or estuarine invertebrates
    - Fish: relatively low acute risk; potential effects to endangered species
    - Invertebrates: high acute risk
    - Fish and Invertebrates: chronic risk high

Disulfoton Freshwater & Estuarine Fish Ecological Risk Characterization

Uncertainties:

- Pond scenario conservative relative to other aquatic habitats
  - Initial concentrations may be higher, residence time may be longer

Disulfoton Freshwater & Estuarine Fish Ecological Risk Characterization (con't)

Uncertainties (con't):

- Freshwater fish chronic toxicity data underestimate sensitivity
  - Fathead much less sensitive than bluegill
  - Fathead acute LC_{50}=4300 ppb
  - Bluegill acute LC_{50}=39 ppb
  - Fathead chronic NOAEC=220 ppb
  - Bluegill if tested, would have lower NOAEC
- Present usage may only minimally expose estuaries

Disulfoton Freshwater & Estuarine Fish Ecological Risk Characterization

- Higher Tier Testing and Incidents
  - **Microcosm**: 27 day LC_{10} for bluegill was 4.7 ppb
    - Modeled scenarios 21 day average residues were 4.3 to 17.9 ppb
  - Only one reported incident (possibly low O_2 level)
  - Fish kill associated with Di-Syston EC application to wheat followed by rainfall
    - Sulfoxide detected at 48 ppb; sulfone detected at 0.2 ppb

Summary of Disulfoton Ecological Risk Assessment

- Granular Formulation -- 15G
  - Acute Risk
    - Overall Summary:

      Small mammal > birds > freshwater invertebrates > estuarine invertebrates > freshwater fish

    - Birds and Mammals:
      - Greatest risk from hand distributed uses
      - Greater risk than soil incorporated, non-granular products

Summary of Disulfoton Ecological Risk Assessment

- Granular Formulation -- 15G
  - Chronic Risk
    - Freshwater invertebrates at greater risk than fish, but recovery is likely
    - No quantitative assessment conducted for birds and mammals

Summary of Disulfoton Ecological Risk Assessment

- Non-Granular Formulation
  - Acute Risk
    - Overall Summary:

      small herbivorous mammals > herbivorous birds > freshwater invertebrates > estuarine invertebrates > freshwater fish > estuarine fish

    - Birds and Mammals:
      - Foliar applications are greater than soil applied, non-granular formulation

Summary of Disulfoton Ecological Risk Assessment

- Non-Granular Formulation
  - Chronic Risk
    - Mammals at greater risk than birds
    - Freshwater invertebrates at greater risk than fish, but recovery is likely

Proposed Changes to Use of Di-Syston 8E

- Cotton at 1 lb ai/A, reduced from three to one applications/season
- Potatoes reduced from 4 to 3 lb ai/A
- Wheat at 0.75 lb ai/A, reduced from two to one applications/season

Proposed Changes to Use of Di-Syston 8E: *Changes in Risk*

- Birds and Mammals:
  - Eliminated High Acute Risk,
  - Chronic risk remains
- Fish: (acute risk not high with current use)
  - Chronic risk reduced
- Invertebrates:
  - Risk reduced, but still high acute and chronic

Summary and Conclusion

Susan Jennings
Team Leader
Special Review and Reregistration Division

Risk Summary: *Food Residues*

- Acute dietary risk at the 99.9th percentile is below the level of concern for all population subgroups
- Chronic dietary risk is below the level of concern for all population subgroups

Risk Summary: *Drinking Water*

- Assessments use estimated concentrations suitable for nation-wide regulation
  - Monitoring data show wide range of detections, reflecting differences in soil vulnerability
  - Assessment may underestimate disulfoton residues in areas with highly vulnerable groundwater

Risk Summary: *Residential*

- Most risks to residential handlers are of concern
  - MOEs are above the level of concern for all scenarios, except handlers of granulars with push-type spreader at lowest application rate

Risk Summary: *Aggregate*

- Aggregate risk from food and water may be above the level of concern
- Risk to handlers is above the level of concern for almost all residential uses
- Aggregate risk would be of even greater concern if residential uses were included

Risk Summary: *Occupational*

- Handlers
  - Risks exceed EPA's level of concern for almost all scenarios (many with MOE's of less than one)
  - Risk to handlers using a tractor drawn spreader at the lowest application rate is the only scenario not of concern

Risk Summary: *Occupational*

- Postapplication Workers
  - Risks are low (not of concern) when disulfoton is used at low application rates (REI of 48 hours)
  - EPA does not have sufficient data to evaluate risks at high application rates
    - Estimated REIs for rates > 4 lbs ai/A range from 28 to 32 days

Ecological Risks: *Terrestrial*

- Risks to birds and mammals are of concern
  - Spray formulations applied at ≥ 2 lb ai/A
  - Granular formulations applied at ≥ 3 lb ai/A
- Risk concern to sensitive species at low exposure levels
- Soil incorporation of granular reduces risk

Ecological Risks: *Aquatic*

- Acute and chronic risk concern for invertebrates, fish
- Registrant's mitigation proposal would reduce, but not eliminate risks

Conclusions

- Significant risks for many uses of disulfoton still remain
- The registrant's proposed label changes reduce risks, however, additional mitigation measures are needed

What Can You Do?

- EPA Is Seeking Information on the Feasibility of Registrant's Proposal Of:
  - Reducing application rates for potatoes, wheat, peanuts, and beans
  - Reducing total number of applications for cotton, potatoes, wheat, sorghum, Brussels sprouts, and cauliflower
  - A cap on total amount applied to tobacco
  - Eliminating foliar application on cotton

What Can You Do?

- Provide Information on Additional Mitigation Measures, Such As:
  - Application methods that may reduce risk
  - Engineering controls, such as closed systems (August 1999 PR Notice)
  - Provide benefits information for uses on agricultural crops

Next Steps for Disulfoton

- 60-day public comment period opens with release of risk assessments
- EPA will continue to:
  - Seek public input to address risk issues of concern
  - Meet with interested stakeholders
- After the 60-day public comment period closes, EPA will generate a risk mitigation proposal for disulfoton